UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,791	01/07/2004	Paul Q. Anziano	MTGY0001-101	6578

35145 7590 06/01/2005

COZEN O' CONNOR, P. C.
1900 MARKET STREET
PHILADELPHIA, PA 19103-3508

EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/752,791	ANZIANO, PAUL Q.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 31-42* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,31,33-35,37,38,40 and 41* is/are rejected.

7)☒ Claim(s) *32,36,39 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on March 9, 2005 is acknowledged. The traversal is on the ground(s) that the examiner has not pointed out Group II is unrelated because it requires the nucleic acid of claims 1 or 2 and the Office has failed to show that it can be practiced with a materially different nucleic acid. This is not found persuasive because the product can be used for a different method as specified (Requirement For Restriction, page 3, last full paragraph).

Applicant has elected a product, and thus rejoinder of method claim is possible upon allowance of the product as outlined in the rejoinder notice included in the Requirement For Restriction.

The requirement is still deemed proper and is therefore made FINAL.

Claim 7 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This action is on claims 1-6 and 31-42.

Information Disclosure Statement

A signed and intialed copy of the IDS file April 1, 2004 is enclosed.

Claim Objections

Claims 32, 36, 39, and 42 are objected to because of the following informalities: They depend from rejected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 5, and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to host cells. The claims are not drawn to isolated host cells, thus, when given the broadest reasonable interpretation, read on host cells comprised within a living organism such as a transgenic animal or a human gene therapy patient. It is noted that the specification contemplates gene therapy on page 26, line 27. The specification is not enabling for host cells comprised within either the human patient for gene therapy for the reasons set forth below.

The instant specification does not teach how to overcome problems with in vivo delivery and expression with respect to the administration of the claimed nucleic acids or viral vectors comprising said nucleic acids. The state of the art as of the priority date

sought for the instant application is that in vivo gene delivery is not well developed and is highly unpredictable. For instance Verma et al (Nature, 1997, Vol. 389, pp. 239-242) teach that the Achilles heel of gene therapy is gene delivery. Verma et al state that the ongoing problem is the inability to deliver genes efficiently and to obtain sustained expression (page 2 first full paragraph of printed article copy supplied).

As of the priority date sought, it was well known in the art how to infect or transfect cells in vitro or ex vivo with viral vectors. However, using viral vectors to deliver DNA to an organism in vivo, or using infected or transfected cells to deliver nucleic acids which encode a particular protein sequence to an organism in vivo is in the realm of gene therapy, and as of the priority date sought, highly unpredictable in view of the complexity of in vivo systems

The specification does not remedy any of the deficiencies or the prior art with regard to gene therapy. Given the lack of any guidance from the specification on any of the above issues pointed out by Verma et al. One of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to use the product in gene therapy.

Amendment of the claims to recite "isolated host cell" would overcome this rejection.

Claims 1-6, 31, 33-35, 40, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to nucleic acids with at least 70 or 97% homology to a sequence.

The nucleic acid sequence is 552 bases to encode SEQ ID#2.

The specification only provides SEQ ID# 3 (the junction region of the deletion) as differentiating wild type from exon 3 deleted MnSOD.

There are no other teachings.

The speciation teaches that 70% identity is a level that can be recognized by hybridization. 70% allows for enough changes to read on the undeleted sequence and thus detect non-exon3 deleted sequences. The limitation allows for over 150 base changes or additions or subtractions.

The speciation teaches that 97% identity is a level that can be recognized by high stringency hybridization. 97% allows for enough changes for gaps in the sequence and thus detect non-exon3 deleted sequences. The limitation allows for over 15 base changes or additions or subtractions.

In the instant case, other than SEQ ID 1 (552 bases to encode SEQ ID#2) no other sequences are disclosed that are 70 or 97% of the protein encoding SEQ ID#2.

Thus, only the full sequence of SEQ ID#1 is described such that it can be used.

Claims 1-6, 33, 34, and 40 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for hybridization using SEQ ID#1, does not reasonably provide enablement for hybridization using sequences with homologies less than 100%. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The claims are drawn to nucleic acids with at least 70 or 97% homology to a sequence.

In the instant case, other than SEQ ID 1 (552 bases to encode SEQ ID#2) no other sequences are disclosed that are 70 or 97% of the protein encoding SEQ ID#2.

The state of the art is high in nucleic acid hybridization. The detection of the sequence by hybridization requires detection of the deletion junction. The specification provides no examples of other sequences that have 70 or 97 % identity that can be used to detect the sequence encoding some homology of SEQ ID#2.

The enabling disclosure is clearly not commensurate in scope with these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Clearly there is lack of guidance directing a skilled artisan to practice the instantly claimed methods. Without specific guidance or direction and /or working examples, one of ordinary skill in the art would not be able to reproducibly use the entire scope of the invention as claimed, without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 33, 37, 38, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Heckl *et al.* US 5240847.

The claims are drawn to a nucleic acid sequence encoding a protein 70% identical to SEQ ID #2.

Heckl *et al.* teach a nucleic acid that encodes a protein at least 70% identical to SEQ ID #2 (columns 21-22, Formula IX). The disclosure also teaches cDNA, cloning, vectors, expression control elements, and host cells.

Thus, Heckl *et al.* anticipate the claimed invention.

Allowable Subject Matter

Claims 32, 36, 39, and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MGH
5/25/05

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600